Summary of Safety and Effectiveness
(as required by 21 CFR 807 92)

JAN 21 2009

SOLAR™ Surgical Ablation System
[K082409]

Submitter
EndoPhotonix, Inc
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Eagan, MN 55122
USA

Contact
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Date of Summary	January 14, 2009
Product Code	GEX
Classification Name	Laser Instrument, Surgical Powered
Common Name	Surgical Laser Instrument
Proprietary Name	SOLAR™ Surgical Ablation System

Description of Device:

The SOLAR Surgical Ablation System consists of a Cart, Laser Energy Generator (Laser Generator), Controller, an infusion set and a Track The Track is an intraoperative, sterile, single-use device designed to apply laser energy to tissue The infusion set is a single-use device having a sterile fluid path designed for the delivery of sterile saline solution to the Track laser tip The Track includes a rigid metallic shaft, a flexible track, and an introducer (guiding obturator) The Track further includes a laser compatible optical fiber which attaches to the Laser Generator The emitted laser energy is directed toward the targeted tissue from the end of the optical fiber which rides within the flexible Track The position of the optical fiber in relation to the target tissue is maintained constant by the method of mounting the fiber within the fiber optic housing and the design of the flexible Track itself The black markers on the Track indicate the area of tissue to be ablated and are used to set the positioning of the fiber optic housing within a given area of tissue The lines of ablation are created by independently activating the laser energy between two numbered segments, which are predetermined by the physician when positioning the flexible Track against the targeted tissue

Statement of Intended Use:

The SOLAR™ Surgical Ablation System is indicated for delivery of 810nm, 1064nm or 1083nm laser light to soft tissue, under visualization, during surgical procedures Indications include the ablation, or coagulation of soft tissue

The SOLAR™ Surgical Ablation System Accessories are intended for use in the support of the delivery of laser light to soft tissue during surgical procedures

Warning:

The SOLAR™ Surgical Ablation System is not indicated for the treatment of cardiac arrhythmias

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use Burns can occur if the laser energy is not correctly applied These complications may be serious

Technological Comparison:

The SOLAR Surgical Ablation System was compared to the current ATRILAZE Surgical Ablation System (K081457) and SOLAR Surgical Ablation System (K061489)

Both the currently available device and the SOLAR system as reviewed in this 510(k) are provided sterile with a sterile fluid path for saline delivery at the laser tip Both fiber optic delivery systems utilize the same laser energy generator and are connected via an SMA 905 connector to deliver laser energy to the target tissue

For purposes of this submission, the SOLAR Surgical Ablation System was compared to the following predicate devices

SOLAR Surgical Ablation System (K061489)
ATRILAZE Surgical Ablation System (K081457)

Testing:

Testing demonstrated that adherence to specifications was demonstrated and the lesions obtained using the SOLAR system with 1083nm laser light are substantially equivalent to those obtained with the currently cleared ATRILAZE Surgical Ablation System wavelengths

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2009

Endophotonix, Inc
% Ms Alexandra Calo
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9725 South Robert Trail
Inver Grove Heights, Minnesota 55077-4424

Re K082409
Trade/Device Name SOLAR™ Surgical Ablation System
Regulation Number 21 CFR 878 4810
Regulation Name Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class II
Product Code GEX
Dated January 5, 2009
Received January 8, 2009

Dear Ms Calo

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 **You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance** at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K082409

Device Name SOLAR™ Surgical Ablation System

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Prescription Use__X__ OR Over-the-Counter Use_____
(Per 21 CFR 801 109)

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM 1/21/2009

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082409